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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/693,383

10/24/2003

Shalaby W. Shalaby

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10/30/2008

PFIZER INC.

PATENT DEPARTMENT, MS8260-1611

EASTERN POINT ROAD

GROTON, CT 06340

EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1618

NOTIFICATION DATE

DELIVERY MODE

10/30/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSGro@pfizer.com

Office Action Summary	Application No. 10/693,383	Applicant(s) SHALABY ET AL.	
	Examiner ERIC E. SILVERMAN	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-11 and 13-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9-3-08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' response, filed 9/3/2008, has been received. Claims 1, 3-11, and 13-17 are pending; none of these claims are withdrawn and all are treated on the merits in this action. This action discusses all rejections that are currently pending against the instant claims. Any rejections that were discussed previously and not repeated herein have not been maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-8, 10, 11 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,232,304 to Kim in view of US 5,916,883 to Shalaby for reasons of record and those discussed below

1. New claims 16 and 17

The new claims require that the functional polymer comprise a cyclic oligosaccharide or cyclodextrin, respectively. It is noted that cyclodextrin is a cyclic oligosaccharide. The Kim and Shalaby references all deal with cyclodextrins, and thus render these claim limitations obvious.

2. Response to Applicants' arguments

Applicants' arguments are predicated on the notion that Shalaby's teachings are limited to drugs of high water solubility. Applicants therefore conclude that one would

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not use ziprrasidone, a low solubility compound, as a drug with Shalaby's cyclodextrin-grafted polymer. Applicants point to Shalaby at col. 1, lines 16-20 and 23-27 to support the notion that Shalaby is limited to high-solubility drugs. These portions of the Shalaby patent are reproduced below.

1

ACYLATED CYCLODEXTRIN DERIVATIVES

BACKGROUND OF THE INVENTION

In 1904, Schardinger first characterized cyclodextrins as cyclic oligosaccharides. The α , β , and γ -cyclodextrins, which consist of six, seven, and eight glucose units, respectively, are the most common natural cyclodextrins. 5

Cyclodextrins have been used as inclusion complexes by complexing with a guest compound or molecule as a host compound or molecule. Such inclusion complexes have been used to mask the bitter taste or unpleasant odor of a guest compound, to solubilize a hardly soluble guest compound, to enlarge the stability of a guest compound against heat, light, or air, to stabilize emulsions, or as a sustained release preparation using a hydrophobic alkylated cyclodextrin. See U.S. Pat. No. 4,869,904. However, no one has attempted to make carboxyacylated cyclodextrins, or used such cyclodextrin derivatives to form ionic sustained release compositions. 10 15 20

SUMMARY OF THE INVENTION

In one aspect, the present invention features a cyclodextrin derivative, wherein at least 60 (e.g., between 75 and 100) percent of the free hydroxy groups of the cyclodextrin are acylated with acyl groups where at least one of the acyl groups comprises a free carboxylic group. What is meant by cyclodextrin is a cyclic oligosaccharide. Examples of cyclodextrins include α -cyclodextrin, β -cyclodextrin, or γ -cyclodextrin. 25 30

Contrary to Applicants' assertion, neither the cited portion of Shalaby, nor any other section of that patent, limits the teachings to drugs of high solubility.

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Hypothetically, even if Shalaby exemplifies high-solubility drugs, such as the water soluble peptide of Example 3, the teaching of a preferred or favored embodiment is not a teaching away from alternative embodiments, nor does a reference that omits one element of a combination (or method), without more, teach away. *See Syntex (U.S.A) LLC v. Apotex, Inc.*, 74 USPQ2d 1823, 1830 (Fed. Cir. 2005) (reference enumerating specific surfactants for use in pharmaceutical composition does not teach away from the use of other, non-enumerated surfactants in the same composition). It is clearly erroneous to conclude that Shalaby teaches away from the use of a low-solubility drug.

Applicants next argue that the fact that the claimed elements are present in the prior art is not sufficient to support a conclusion of obviousness, rather the art must provide some reason for the combination. In response, the rejection at hand is not based on the mere presence of the claimed drug and the claimed polymer conjugate in the prior art. On the contrary, Shalaby specifically calls for a drug with ionizable group, such as an ionizable amine, for conjugation with the cyclodextrin polymers disclosed therein. Kim provides such a drug, ziprasidone, and also teaches that this drug can be conjugated with cyclodextrins. The instant invention is therefore no more than the use of a drug in Shalaby's polymer-drug conjugate, where the drug used (ziprasidone) has all of the characteristics identified by Shalaby for drugs usable in said conjugates.

MPEP 2144.06 states that "selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." (citing *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327 at 335, 65 USPQ 297 at 301.) The case at hand is analogous; the claims involve no more than

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finding a drug meeting Shalaby's requirements and using that drug in a manner called for by Shalaby. Applicants also argue the cyclodextrin grafted polymer, while an integral part of the prior art relied on, is not integral to the claimed invention. This argument is not germane. All of the claims read on polymers with grafted cyclodextrin, new claims 16 and 17 included, and Applicant has not argued to the contrary.

Applicants also argue that neither reference anticipates the instant claims. The issue at hand is not one of anticipation, but of obviousness. It is well established that a reference need not anticipated a claim to render the same claim obvious. It is also established that an obviousness rejection based on more than one reference cannot be overcome by looking at the references individually.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

Eric E. Silverman

Art Unit 1618